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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,357	08/27/2003	James Dillon	070050.2882	6693

21003 7590 08/09/2006

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EXAMINER

KHANNA, HEMANT

ART UNIT PAPER NUMBER

1654

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,357

Applicant(s)

DILLON, JAMES

Examiner

Hemant Khanna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of claims 1-23 that belong to Group I in the reply filed on June 20, 2006 is acknowledged.

Claims 1-23 are pending.

Claims 24-30 are withdrawn from further consideration as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on June 20, 2006.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: measurement of oxygen concentration levels before vitrectomy, directly after vitrectomy, and during the surgical procedure. Further method steps involve the use of a vitrectomy cutting instrument, for cutting and removing a part of the vitreous, followed by degassing of the replacement solution, and introduction of a degassed aqueous solution having glutathione and/or ascorbic acid into the eye.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Gan et al (USPN 5,523,316).

The claims are drawn to methods that comprise the use of a vitreous replacement solution having a low oxygen concentration.

Gan et al describe ophthalmic irrigating solutions and methods in connection with ophthalmic surgical procedures comprising antioxidants such as, glutathione and ascorbic acid, to control intraocular pressure during cataract surgery or other intraocular surgical procedures (abstract, column 7, lines 60-65). The intraocular surgical procedure and ophthalmic irrigating solutions meet the limitations of the method involving a vitreous replacement solution as claimed by the applicant. In view of the similarity in replacement solution, and absence of method steps in the recitation of the method claims, the inclusion of glutathione and ascorbic acid in the ophthalmic irrigating solution as taught by Gan et al will inherently result in the claimed oxygen concentrations. The concentration of oxygen in the replacement solutions in presence of antioxidants is directed to an existing property of the solution. Therefore, it is pointed out that variations in concentration of oxygen would reasonably have been anticipated. Hence, the Gan et al reference meets all the process limitations of the claimed invention. See MPEP 2112.02.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 4-8, and 18-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al (USPN 5,523,316) in view of Calvin et al (Exp. Eye Res. (1997) 65:341-347).

The claims are drawn to methods that utilize a low oxygen concentration solution that comprises glutathione and ascorbic acid to protect against cataract.

Gan et al describe ophthalmic irrigating solutions and methods in connection with ophthalmic surgical procedures comprising antioxidants such as, glutathione and

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ascorbic acid, to control intraocular pressure during cataract surgery or other intraocular surgical procedures (abstract, column 7, lines 60-65). The glutathione and ascorbic acid correspond to the applicant's compounds that comprise a solution of low oxygen concentration. Gan et al do not explicitly teach the concentrations of glutathione or ascorbic acid that yield a low oxygen concentration solution.

Calvin et al teach cataracts promoted by injections of buthionine sulfoximine, which were accompanied by reduction of lens glutathione (reduced) levels. Further, Calvin et al teach that the above-mentioned cataracts were also completely prevented by 1 mM ascorbate or 2 mM glutathione (reduced).

It would have been obvious to one of ordinary skill in the art to modify the replacement solutions utilized in ophthalmic surgical procedures as taught by Gan et al with concentrations of reduced glutathione and ascorbic acid known to prevent cataract, as taught by Calvin et al. One would have been motivated to use low oxygen concentration solutions fortified with reduced glutathione and ascorbic acid in view of the teachings of Gan et al who suggest the use of such solutions to prevent the elevation in intraocular pressure from the photochemical generation of oxygen radicals that occurs during intraocular procedures, such as cataract surgery (column 7, lines 55-65). There would have been a reasonable expectation of success in view of the teachings of Calvin et al who teach the prevention of oxidative cataract induction by the presence of reduced glutathione.

6. Claims 9-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Gan et al (USPN 5,523,316) in view of Komiya (Synthesis of Organometallic compounds: A Practical Guide, John Wiley & Sons (UK), 1997, page 35-50).

The claims are drawn to methods that utilize a vitreous replacement solution that comprises a solution of low oxygen concentration from which a portion of the oxygen has been removed.

Gan et al describe ophthalmic irrigating solutions and methods in connection with ophthalmic surgical procedures comprising antioxidants such as, glutathione and ascorbic acid, to control intraocular pressure during cataract surgery or other intraocular surgical procedures (abstract, column 7, lines 60-65). The glutathione and ascorbic acid correspond to the applicant's compounds that comprise a solution of low oxygen concentration. Gan et al do not explicitly teach subjecting the irrigating solution to partial vacuum or to the presence of inert gases to reduce the levels of oxygen.

Komiya teach many techniques for handling of air- and moisture sensitive compounds, which are known to one of ordinary skill in the art. Komiya disclose techniques that comprise making an inert atmosphere by bubbling Ar or N₂ gas into the solution (Introduction, page 35), or techniques that involve the use of vacuum lines (Basic Apparatus, Vacuum and Nitrogen lines, page 35) to remove any traces of air, or those that involve the use of specialized glassware (Schlenk technique, page 40) to facilitate experimental work to be done under an inert atmosphere.

It would have been obvious to one of ordinary skill in the art to modify the low concentration oxygen solutions comprising glutathione and ascorbic acid as taught by Gan et al with methods to remove trace levels of oxygen, as taught by Komiya. One would have been motivated to remove trace levels of oxygen because oxidized glutathione is unstable over extended periods of time (column 3, lines 50-52). There would have been a reasonable expectation of success in view of the teachings of Gan et al to prevent the elevations in intraocular pressure from the photochemical generation of oxygen radicals that occurs during intraocular procedures, such as cataract surgery.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



HK
August 2, 2006



ANISH GUPTA
PRIMARY EXAMINER